DEPARTMENT OF HEALTH AND HUMAN SERVICES

943650

Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
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October 15, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 04 - 02

Richard Renier, President/Co-Owner
Brian J. Neuser, Chief Operating Officer/Vice President
The Earl of Sandwiches
106 Wildwood Road, P.O. Box 658
Willernie, Minnesota 55090

Dear Messrs. Renier and Neuser:

On June 19, 24, 25, and July 1, 2003, we inspected your seafood processing facility located in Willernie, Minnesota. We found that you have serious deviations from the seafood Hazard Analysis and Critical Control Points (HACCP) Regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of the HACCP regulations, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C § 342(a)(4). Accordingly, your Tuna Sub is adulterated, in that the product has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. You may find the Act and its implementing regulations through links in FDA's home page at www.fda.gov. In addition, several of your products are misbranded within the meaning of Sections 403(e)(2) and 403(f) of the Act.

The deviations noted on the issued FDA-483, Inspectional Observations, which cause your product to be adulterated are as follows:

1. You must have a HACCP plan that, at a minimum, lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for Tuna Sub lists a monitoring frequency at the Storage critical control point that is not adequate to control pathogen growth. Your HACCP plan lists that you will monitor your walk-in cooler

temperature once a day. FDA currently recommends that storage temperatures for ready-to-eat seafood, such as your Tuna Sub, be monitored continuously. Examples of continuous monitoring methods include, but are not limited to, high temperature alarms or continuous temperature data loggers.

2. You must implement the monitoring procedures that you have listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not follow your HACCP plan's monitoring procedure for storage temperature to control pathogen growth for your Tuna Sub. Your plan lists that the manager will check the temperature of the cooler daily. Our review of your record has determined that your firm failed to monitor your cooler according to your plan, in that during several scheduled production days, the temperature of your cooler was not recorded on your monitoring record, "Cooler Temp Tracking Chart Main Walkin."

3. You must maintain sanitation control records that, at a minimum, document monitoring and prescribed corrections, to comply with 21 CFR 123.11(c). However, your firm did not maintain daily sanitation records monitoring the eight key areas of sanitation required for the processing of the Tuna Subs you processed from January 2001 through July 1, 2003.

We also note that several of your products are also misbranded under the Act. The following products are misbranded within the meaning of 403(e)(2) of the Act in that the labels do not contain the net weight declaration required under that Section and 21 CFR 101.105(a): Chicken Cordon Bleu; Sloppy Joe & Cheese; ½ lb Bacon Cheeseburger; ½ lb Cheeseburger; Ham & Swiss on Rye; Ham & Swiss on Wheat; Ham & Cheese on White; Turkey on Wheat; and Chuckwagon.

In addition, several of your products are misbranded within the meaning of Section 403(f) of the Act in that the labeled listing of ingredients is in a font size smaller than that required under 21 CFR 101.2(c), i.e., 1/16 inch in height. These products are: Chicken Cordon Bleu; Sloppy Joe & Cheese; ½ lb Bacon Cheeseburger; ½ lb Cheeseburger; Chili Dog; Tuna Sub; and Smoked Ham with Swiss.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product and/or enjoin your firm from operating.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation or other useful information that would assist us in evaluating your corrections. If you cannot

complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act and all implementing regulations. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to Compliance Officer Tyra S. Wisecup at the address in the letterhead. If you have questions regarding any issue in this letter, please contact Compliance Officer Wisecup at (612) 758-7114.

Sincerely,

W. Charles Becoat
Director
Minneapolis District

TSW/ccl